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EXAMINER

TUNG, P

ART UNIT	PAPER NUMBER
	1652

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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<b>Office Action Summary</b>	Application No. <b>08/951,188</b>	Applicant(s)	Price
	Examiner <b>Peter Tung</b>	Group Art Unit <b>1652</b>	

Responsive to communication(s) filed on Oct 4, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 110-216 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 110, 113-124, and 133-216 is/are rejected.

Claim(s) 111, 112, and 125-132 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1652

## **DETAILED ACTION**

1. Claims 110-216 are pending.

### *Claim Objections*

2. Claims 203-207, 209 and 210 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

3. Claim 173 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 137, from which claim 173 depends upon, recites the limitation of the nucleic acid molecule encoding a P-TEFb large subunit protein. Claim 173 does not have this limitation.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1652

5. Claims 137-148, 173-176, 181-183, 185-202, 208 and 211-216 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "stringent ... conditions" in claims 137, 173, 181-183 and 190 is a relative term which renders the claim indefinite. This rejection is explained in the prior Office action.

7. Applicants argue that there is no prohibition of using relative terms to define an invention and that it is the role of the specification to describe the invention. Additionally, applicants argue that hybridization is a routine operation and those of skill in the art clearly know various ways of performing stringent hybridizations.

8. Applicant's arguments filed 10/4/99 have been fully considered but they are not persuasive. The relative term in the claims used to define the invention is problematic because it renders the metes and bounds of the claim indefinite. While it is the role of the specification to describe the invention, when exemplary conditions and not definitive conditions are provided in the specification, the description of the invention is indefinite. Even though hybridization may be a routine operation and those skilled in the art clearly know various ways of performing stringent hybridizations, the claim is still indefinite because specific conditions for the hybridization have not been provided in the claims. The routineness of hybridization does not address the many ways hybridization can be done and how the results obtained from a hybridization are dependent upon the specified conditions. A person skilled in the art would require hybridization conditions in

Art Unit: 1652

order to interpret the results of a hybridization and to determine the metes and bounds of the instant claims.

9. Claims 138-148, 174-176, 184-189 and 191-202, 208 and 211-216 are indefinite because they depend upon an indefinite base claim and fail to correct the problem.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 137-148, 173, 181-184, 190, 194, 195-202 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific SEQ ID NO: or a DNA which encodes a specific SEQ ID NO:, does not reasonably provide enablement for a cDNA which hybridizes to a specific SEQ ID NO: or DNA encoding a specific SEQ ID NO:. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is explained in the prior Office action.

12. Applicants argue the amended claims overcome this rejection.

13. Applicant's arguments filed 10/4/99 have been fully considered but they are not persuasive. With no specific hybridization conditions provided, those DNAs which hybridize to a specified SEQ ID NO: are not enabled.

14. Claims 149-151, 157-163, 177-184, 190, 194-202, 208 and 211-216 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding the

Art Unit: 1652

specific SEQ ID NOS, does not reasonably provide enablement for DNA encoding proteins with 90 to 99% identity to the specific SEQ ID NOS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Insufficient guidance is provided on how to calculate percent identity between two sequences. Without this guidance, a large amount of experimentation would be required to determine what proteins would have 90-99% identity to the specified sequences. Insufficient examples are provided of proteins which are 90-99% identical to the proteins of the instant claims. Insufficient examples are provided of P-TEFb large subunit proteins which are 90-99% identical to the specific SEQ ID NOS and which still form a complex and promote transcriptional elongation. The relative skill of those in the art is low in making a protein with the same function as a protein that is less than identical in amino acid sequence. A large amount of experimentation would be required to determine how to make and use such a protein if it is unable to function in a P-TEFb enzyme. There is unpredictability in the art in determining percent identity between two proteins absent an algorithm for determining percent

Art Unit: 1652

identity and parameters for that algorithm. Additionally, there is unpredictability in the art in making a functional protein with changes to the amino acid sequence, absent any guidance on where changes can be made to the sequence. The breadth of the claims encompasses changes in the specified amino acid sequences of 1-10%. A large amount of experimentation would be required to make a protein with 1-10% amino acid changes and still function in a P-TEFb enzyme. The scope of the claims is beyond the enabling scope of the disclosure.

15. Claims 181-183 and 185-202 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide encoded by SEQ ID NO: 1 or 5, does not reasonably provide enablement for a polynucleotide which hybridizes to SEQ ID NO: 1 or 5 and which encodes a polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the relative skill of those in the art, (6) the predictability or unpredictability of the art, and (7) the breadth of the claims. The breadth of the claims encompass any polynucleotide which encodes a protein and which hybridizes to SEQ ID NO: 1 or 5. Insufficient guidance is provided on proteins besides those encoded by SEQ ID NO: 1 and 5. With insufficient guidance, a large amount of experimentation would be

Art Unit: 1652

required to determine how to use proteins encoded by nucleotides which hybridize to SEQ ID NO: 1 or 5. Insufficient examples are provided on how to use proteins which hybridize to SEQ ID NO: 1 or 5. As there is unpredictability in determining what nucleotides will hybridize to SEQ ID NO: 1 or 5 and whether the hybridized nucleotides would encode a protein, a large amount of experimentation would be required. The relative skill of those in the art is low in determining how to use proteins based only on the ability of the encoding polynucleotides hybridization to a specific nucleotide sequence. Based upon the limiting scope of the disclosure, undue experimentation would be required to enable the full scope of the claims.

*Claim Rejections - 35 USC § 102*

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 110, 113, 114 and 133-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al. (Ref. U) Hillier et al. teach a polynucleotide which encodes a polypeptide comprising 18 amino acids of SEQ ID NO: 45 and a polynucleotide which encodes a polypeptide comprising 18 amino acids of SEQ ID NO: 47. Hillier et al. also teach that the polynucleotides are cloned in a pT7T3 expression vector. Additionally, the other nucleotides

Art Unit: 1652

which do not encode the 18 amino acid portions of SEQ ID NO: 45 and 47 can be considered the second coding region. Hillier et al. therefore anticipate the instant claims.

18. Claims 110, 113, 114-124 and 133-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al. (Ref. V) Hillier et al. teach a polynucleotide which encodes a polypeptide comprising 104 amino acids of SEQ ID NO: 50. Hillier et al. also teach that the polynucleotide is cloned in a pT7T3 expression vector. Additionally, the other nucleotides which do not encode the 104 amino acid portions of SEQ ID NO: 45 and 47 can be considered the second coding region. Hillier et al. therefore anticipate the instant claims. which is that of the instant claims.

19. Claims 111, 112, 125-132, 144-146, 164-172 and 174-176 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. No claims are allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1652

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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